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ESTTA288875 06/09/2009

Filing date:

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91177234
Party	Plaintiff Cardinal Health 303, Inc.
Correspondence Address	Joseph R. Dreitler Bricker & Eckler LLP 100 S. Third Street Columbus, OH 43215-4291 UNITED STATES mtrue@bricker.com
Submission	Plaintiff's Notice of Reliance
Filer's Name	Mary R. True
Filer's e-mail	trademarks@bricker.com
Signature	/Mary R. True/
Date	06/09/2009
Attachments	Burns Notice_pdf (7).pdf ( 20 pages )(3278731 bytes )



## newsletter

Hoyo Memorial Hospital and Health Services

# "Smart" Technology Increases Patient Safety

In early December, Floyd Memorial became the first health care facility in the Kentuckiana area to implement the ALARIS Medical Systems Medley<sup>TM</sup> Medication Safety System with Guardrails<sup>®</sup> Safety Software. Together, the two systems are designed to reduce errors in the administration of intravenous (IV) medications. The installation of the equipment reflects the hospital's continued commitment to providing the highest standard of patient safety and quality care.

The Medley<sup>TM</sup> Medication Safety System with the Guardrails<sup>®</sup> Safety Software acts as an "assistant" to nurses who administer IV medications at the point of care. As a health care provider enters dosage information into the system, the software accesses the health system's drug library and compares the order against a preset standard for minimum and maximum doses. Anything above or below the pre-established limits will result in an alert to the nurse.

"To err is human' is a popular quote for a good reason," said Chris Beeles, R.N., clinical educator at Floyd Memorial. "No matter how many precautions we take, we can never completely eliminate human error. That is where technology comes into the picture."

The ALARIS® Medley™ System is one of the most preferred systems according to a valuative study performed by ECRI, a health services research agency.

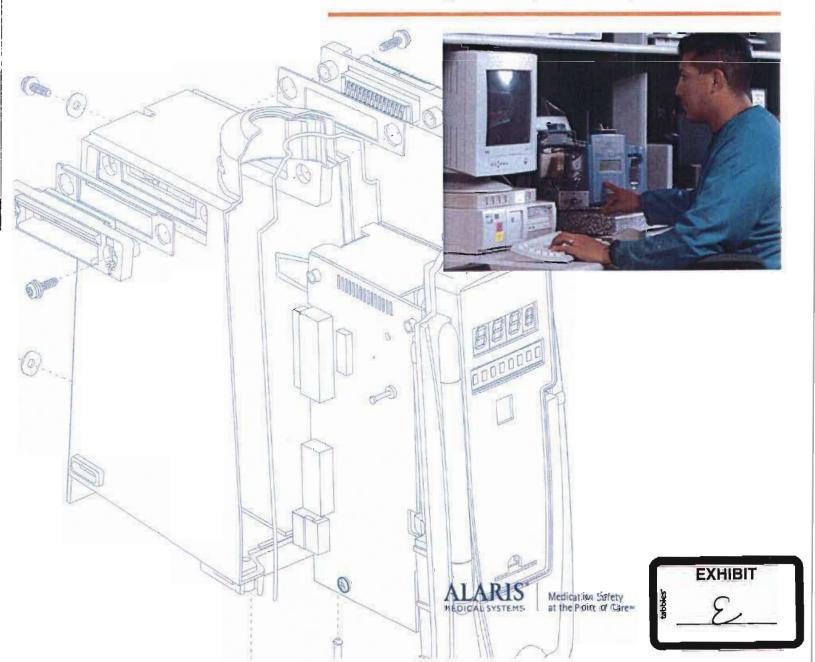
Copyright © 2003 Floyd Memorial Hospital and Health Services. All rights reserved.

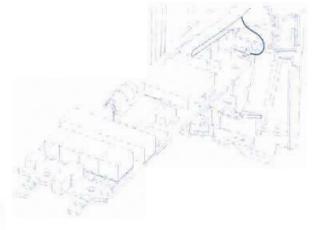
Floyd Memorial Hospital and Health Services 1850 State Street New Albany, IN 47150 812.944.7701 ALARIS° FISA

Parts and Repair

Manage Your Post-Warranty Cost with FISA, a BioMedical Cost Management Solution.

> The ALARIS® Flexible Instrument Service Agreement (FISA) provides your facility with a unique way to manage parts and service costs by offering you the flexibility to chose how and when you utilize parts and repair services.





# Pay Only for What You Use

Rather than buying a flat-rate contract on your equipment, pay only for what you use. The FISA Parts and Repair plan allows you to anticipate usage based on your department's current staffing and workflow. You can pre-pay anticipated costs at a discounted rate. Then you decide how and when to use those dollars.

# Flexibility with Budgetary Control

Parts and repairs will be billed against the FISA Parts and Repair plan until the purchased amount is consumed. As a FISA Customer, you will receive a quarterly statement that details recent charges and updates your account balance. FISA does not expire, and you can replenish your account at any time. Using the FISA plan also creates an ongoing record of parts and repairs to help you monitor post-warranty service activity.

Customizing your Account

ALARIS® Sales and Service staff will assist you in determining the amount of your initial FISA purchase by evaluating the size of your facility, past parts and service requirements, and your choice of primary service type—Depot, On-Site, Parts Purchase or Preventative Maintenance.

FISA is available for select models and locations. For more information, contact ALARIS Medical Systems, Inc. at 1-800-482-4822, Fax 1-858-458-7760, or visit our web site at www.alarismed.com/na

ALARIS Medical Systems, Inc. Worldwide Headquarters, 10221 Wateridge Circle, San Diego, California 92121-2772

ALARIS

Medication Safety

Fax: 1-858-458-7760 Customer Service: 1-800-482-4822 Website: www.alarismed.com/na ALARISE and ALARISE Medical Systems are regis tered trademarks ALARIS Medical Systems, Inc.



ALARIS MEDICAL SYSTEMS, INC.

CORPORATE OFFICE: 10221 WATERIDGE CIRCLE, SAN DIEGO, CALIFORNIA 92121

CUSTOMER SERVICE: 800-482-4822

INSTRUMENT / DISPOS	ABLES AGREEMENT	P.O. NUMBER
This Instrument / Disposables Agreement ("Agree") ("ALARIS Medical") and:	eement") is between ALARIS Medical Systems, Inc.	
BILLING ADDRESS	"Customer".  SHIPPING ADDRESS (if there are multiple shipping addresses, attach separate sheet)	FOR ALARIS MEDICAL USE ONLY  Acct Cons./Alt. Site No.
STREET	STREET	Name
Officer	5.00	Group No. or Name Customer No.
CITY STATE ZIP	CITY STATE ZIP	Agreement No.
	A T	Start Date
AREA TELEPHONE EXT.	AREA TELEPHONE EXT.	Expiration Date
		Service Agreement No.
	TAX EXEMPT Yes No	Quote No.

This Agreement is effective as of the date indicated on the ALARIS Medical signature line below (the "Effective Date") and shall continue in effect for a period of months (the "Term").

We agree to the terms and conditions in this Agreement, including the standard terms and conditions on the reverse side, with respect to the purchase of ALARIS Medical's disposables and instruments (the "Products").

- PURCHASE: Customer will accept deliveries and pay for the Products ordered at the prices in Section IV and in accordance with all of the terms of this Agreement.
- PRICING: ALARIS Medical guarantees the prices below during the Term provided that Customer complies with all of the terms and II. conditions of this Agreement. If Customer orders the Products through a distributor, the prices below will not be available from ALARIS Medical to the distributor until forty-five (45) days after the Effective Date. Prices for the Products are net of all discounts and other programs including group pricing, if any.
- PURCHASE COMMITMENT: Customer's unit prices are based upon the following purchase commitments: (A) Customer agrees to W. purchase at least the Annual Quantity of each model of the Compliant Disposables in Section IVB (together, the "Total Annual Quantity") during each 12 month period of the Agreement; and (B) Customer agrees to purchase at least the Agreement Quantity of the Compliant Disposables during the Term. The "Agreement Quantity" shall mean the Total Annual Quantity + 12 x the total number of months in the Term.
- PRODUCTS: IV.

#### A. INSTRUMENTS

The costs of the instruments are only distributed over the Compliant Disposables set forth in Section IV (B) and only the Compliant Disposables will count toward the Agreement quantity. ALARIS Medical will provide to customer the following ALARIS Medical Instruments ("Instruments") for use during the Term of this Agreement:

	MODEL NUM	BER	NEW	REFINANCED		QUANTITY
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				TOTAL QUANTITY	′	

WHITE: CUSTOMER SERVICE

GREEN: AREA MANAGER

CANARY: ACCOUNT CONSULTANT

PINK: CUSTOMER FINAL

GOLDENROD: CUSTOMER PRELIMINARY

Do Not Write in This Space

SEE TERMS & CONDITIONS ON BACK OF PAGE 2 OF 2

	. COMPLIANT D	ISPOSABLES		District Contract	SELECTION AND ADDRESS.
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TOTAL AND	HIAI				
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Med requ	dicals' warranty policulested as noted belo tended Service Opt	cies in effect at time of Ir	nstrument shipment. Extend on terms are provided under ed herein):	ded service options with pri-	ument warranty per ALARIS cing incorporated herein are
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	NO E	xtended Service Option i	Requested (ALARIS Medical	standard warranty only)	
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ei C	NATURE	TYPED OR PRINTED	NAME	TITLE	DATE
	MEDICAL USE ONLY:	THEO ON TRIVIEL			
By:					
	NATURE I BEHALF OF ALARIS MEDI	TYPED OR PRINTEE CAL)	NAME	TITLE	EFFECTIVE DATE
WHITE: CUSTOMER	SERVICE GREEN:	AREA MANAGER CA	NARY; ACCOUNT CONSULTANT	PINK: CUSTOMER FINAL	GOLDENROD: CUSTOMER PRELIMINARY

Page 2 of 2

Rev. 4/00

SSM #302

#### STANDARD TERMS AND CONDITIONS - Instrument Disposables Agreement

- 1. RIGHTS TO INSTRUMENTS: With respect to the Instruments, Customer does not acquire title to or ownership in the Instruments until the purchase terms of this."

  Agreement have been satisfied in full. To secure the timely payment and performance of all obligations of Customer under this Agreement, including those set forth on the signature page hereof, Customer hereby grants to ALARIS Medical a security interest in all Products shipped or sold at any time to Customer under this Agreement, to order to protect ALARIS Medical's security interest and ownership rights in the Instruments, Customer agrees to the filing of UCC-1 or other forms for the purpose of providing notice to Customer's creditors of ALARIS Medical's prior rights to the Instruments. Customer agrees to the filing of UCC-1 forms on its behalf. Until Customer takes title, the Instruments will not be sold or otherwise transferred, except as between parties to this Agreement, without ALARIS Medical's prior written consent. Notwithstanding the foregoing. Customer shall pay and be responsible for all property or similar taxes imposed on the Instruments while this Agreement is in effect. ALARIS Medical shall be permitted to display notice of its ownership of the Instruments by affixing to each item an identifying stencil or plate or any other indicia of ownership and Customer will not alter, deface, cover or remove such ownership identification. Customer shall maintain insurance coverage on the Instruments for the full Term of the Agreement.
- 2. WARRANTY: ALARIS Medical warrants to Customer that the Products shall conform to specifications as published at the time of purchase. ALARIS Medical shall have the right to substitute another ALARIS Medical product for any Product, provided the substitute product shall have the same function at the same price as the Product. Unless otherwise agreed to in writing, ALARIS Medical's sole liability under this warranty shall be to replace or repair, at ALARIS Medical's election, defective Products within one (1) year of the date of delivery, free of charge. ALARIS MEDICAL DISCLAIMS ANY OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ALARIS Medical further disclaims any liability for any special, incidental or consequential damages including loss of use, profit, business or goodwill caused by or related to Products, or any damage due to misuse, abuse or negligence by Customer.
- 3. TERMINATION/CANCELLATION/NONCOMPLIANCE: Subject to the following, either party may terminate this Agreement at any time by giving the other party written notice at the address on the reverse side of its intent to terminate at least sixty (60) days prior to the intended termination date:
- A in the event that Costomer terminates this Agreement of in the event that Costomer has not purchased the Agreement Quantity of the Compliant Disposables by the conclusion of the Term, Costomer agrees to within 60 days of such termination or conclusion of the Term pay to ALARIS. Medical (i) an Administrative Charge (defined below) based on the difference between the Agreement Quantity of Compliant. Disposables and the quantity of Compliant. Disposables and the quantity of Compliant. Disposables and the quantity of Compliant Disposables actually shipped to und paid for by Customer and (ii) the Remaining Instrument Revenue. The "Administrative Charge" shall mean a charge of two dellars (\$2.00) per each LV.

  disposable Product or \$10.00 per 1,000 probe covers, as applicable. The "Remaining Instrument Revenue" shall mean the unpaid principle and interest due for each month of the Term.
- B. If Customer breaches any material provision of this Agreement (including failure to pay), ALARIS Medical shall give notice of the breach, and if not remedied within sixty (60) days of the date of the notice, ALARIS Medical, in addition to all other available remedies, shall have the right to terminate this Agreement immediately. In such event, Customer agrees to pay ALARIS Medical within 60 days of such termination (i) the Administrative Charge based on the difference between the Agreement Quantity of Compliant Disposables and the quantity of Compliant Disposables actually shipped to and paid for by Customer, and (ii) the Remaining Instrument Revenue.
- C. If Customer fails to purchase at least the Total Annual Quantity of the Compliant. Disposables during each twelve (12) month period of the Agreement, ALARIS Medical reserves the right to bill the Customer (including against Customer's existing purchase order) and Customer agrees to pay within sixty (60) days (i) the Administrative Charge based on the difference between the Total Annual Quantity of the Compliant. Disposables and the quantity of Compliant Disposables and the quantity of Compliant Disposables and the quantity of Compliant Disposables. Customer agrees to purchase the duantity of Compliant Disposables, Customer agrees to purchase that quantity of Compliant Disposables, determined by ALARIS Medical in its sole discretion, necessary to compensate ALARIS Medical for any finance costs associated with extending Customer's purchases beyond the Term.
- D. If this Agreement is terminated prior to the end of the Term as a result of Customer's breach, Customer shall, in addition to all other charges bereunder, also pay ALARIS Medical the Administrative Charge for all unpurchased Additional Disposables.
- E. In the even that the parties agree to writing to extend the Term, ALARIS Medical reserves the right for each inhequent twelve (12) month period or portion thereof to increase the price for each disposable Product by an amount equal to the percentage increase in price for such Product as between the previous two twelve month periods.
- F. Product usage during the Term of this Agreement may change due to changes in hospital ceasus or protocols. If a material change in the volume of Product usage occurs, upon Customer's request and ALARIS Medical's receipt of modified ceasus statistics and/or proof of protocol change, ALARIS Medical may agree to negotiate an edjustment to the Term, quantities, and/or prices upon ALARIS Medical's verification and approval of the information provided.
- G. In the event any litigation is brought for breach of this Agreement, the prevailing party also shall be entirled to its reasonable costs and attorneys' fees.
- 4. RETURNED GOODS POLICY: All returns must be authorized by ALARIS Medical and must be made in accordance with ALARIS Medical's then-current policy on returned goods in effect at the time return is sought. No returns will be accepted without prior authorization.
- 5. DELIVERY AND SHIPMENT: Products will be delivered to Customer's shipping address as set forth in this Agreement. All shipments of Products will be FOB ALARIS Medical shipping point (distribution facility). Customer authorizes ALARIS Medical to proper freight charges on Customer's behalf. Customer agrees to reimburse ALARIS Medical for such freight charges. All orders are subject to ALARIS Medical's then-current policy on minimum orders in effect at the time the order is placed.

#### 6. MISCELLANEOUS TERMS AND CONDITIONS:

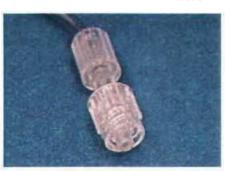
- A. This Agreement is governed by the laws of the State of California. This Agreement contains the entire Agreement between Customer and ALARIS Medical, and supersedes all prior proposals and agreements for the Products between the parties, whether oral or written.
- B. Contomer expressly agrees that ALARIS Medical shall have the right, in its sole and absolute discretion, to assign this Agreement to a third party. This Agreement shall be binding upon end many to the benefit of the parties' successors and assigns.
- C. This Agreement is not effective until signed by an authorized representative at ALARIS Medical. No changes to the Agreement shall be effective unless such changes are set term in a section amendment to the Agreement which has been signed by both parties. Any waiver of a breach of any provision of this Agreement shall not be decreed to be effective unless signed by the party against whom enforcement of such waiver is sought. Both parties acknowledge and agree that this Agreement appeare less the terms and conditions of any porchase order used by Classomer, but Customer may place orders by use of purchase orders for Customer's convenience and to comply with Customer's internal procedures and requirements. Any additional or different terms and conditions submitted by Customer to ALARIS Medical in such purchase order or acceptance shall be deemed objected to by ALARIS Medical and shall be of no effect nor in any circumstance binding upon ALARIS Medical.
- D. If the pricing under this Agreement constitutes any discounts or other reductions in price under Section 1128(b)(3)(A) of the Social Security Act 42 U.S.C. 1320a-7b(b)(2)(A). Customer shall disclose the discounts or reductions in price under any state or federal program which provides cost- or charge bissed reimbursement to Customer for Products covered by this Agreement.

# TWO-PIECE LUER LOCK

#### TIP SHEET

ALARIS™ Medical Systems has implemented a **new two-piece luer lock** for the infusion pump administration sets and gravity sets. This luer may be used for one-piece connection or as a two-piece luer. This tip sheet includes instructions in using the new two-piece luer.

**New Luer** 



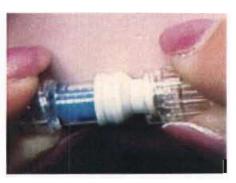
**Previous Luer** 



Using Luer as a One-Piece Luer



I. Slide luer lock forward.



2. Secure luer lock to vascular access device.

#### Using Luer as a Two-Piece Luer



I. Slide luer lock back.



2. Insert luer slip to vascular access.

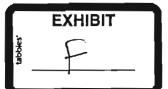


3. Secure luer lock to vascular access device.

#### **Precautions:**

- · Use aseptic technique.
- · Follow appropriate administration set directions for use.
- · Ensure luer is securely attached to patient's vascular access device.

Contact the ALARIS™ Medical Systems STATLine at (800) 854-7128 for assistance.





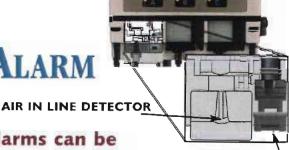
the Quality of Human Life™

ALARIS Medical Systems, Inc.
10225 Waterine Curle

10221 Wateridge Circle San Diego, California 92121-2772 Customer Service: (800) 482-4822 FAX: (858) 458-7760 Website: WWW.ALARISMED COM

# MedSystem III®

# TROUBLESHOOTING A "PUMPING LATCH CLOSED" ALARM



ALARIS

PUMP LATCH

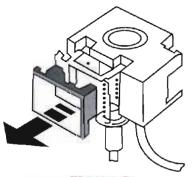


Figure A
CASSETTE SLIDE CLAMP

# Pumping latch closed alarms can be reduced with the following practices:

- Turn the pump on before inserting the cassette into the pump.
- Be sure to angle the cassette up and in when loading.
- Stop the channel **before** removing the cassette from the pump.
- Fully extend the cassette slide clamp when removing the cassette from the pump. (See Figure A).

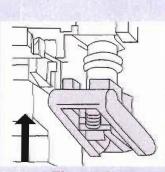


Figure 1
PUMPING LATCH CLOSED



Figure 2
CORRECTIVE ACTION

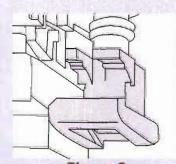


Figure 3
PUMPING LATCH OPEN

Note: Illustrations are shown with protective base cover removed.

### To address a "Pumping Latch Closed" alarm: (See Figure 1)

- Use only your finger to push down the closed pumping latch jaw until it snaps open. (See Figure 2)
- If the pumping latch jaw is visibly broken, the channel may be disabled by pressing the "Service" key.
- ✓ Do not press the "Service" key unless you wish to disable the channel.







# Cleaning the Air-in-Line Detector

It may be necessary from time to time to clean the Air-in-Line Detector so that optimal contact is maintained between the detection system and the I.V. tubing. This allows the ultrasound emitter in the Air-in-Line arm to send a clear signal through the I.V. tubing to the receiver.

Cleaning can be accomplished using a cotton-tipped applicator moistened with water. Do not use chemical cleaners or solvents.

- Open the instrument latch.
- Moisten a cotton-tipped applicator with warm water.
- Holding the wooden shaft of the applicator vertically, with the tip upward, place the cotton tip over the air-in-line detector. (Figure A)
- Close the latch so that the tip of the applicator is enclosed between the air-in-line detector and the air-in-line arm. (Figure B)
- Swab up and down at least three times.
- Open the latch and remove the applicator.









# Midstream Occlusions

# Why it happens, what to do, how to minimize it

#### WHAT IS IT?

A midstream occlusion is an obstruction to the infusion tubing's lumen within the pumping segment.



#### WHY DOES IT OCCUR?

If the pump segment tubing is held under fixed compression for prolonged times, on occasion it will fuse closed. The effect is directly related to the amount of time the tubing spends in a compressed state.

#### WHAT HAPPENS NEXT?

The Medley™ System is designed to detect midstream occlusions. When a midstream occlusion is detected the Medley™ System will alarm and a message will be displayed. In most cases the lumen may be re-opened by physically massaging the tubing.

#### MIDSTREAM OCCLUSIONS ARE MOST LIKELY TO OCCUR:

- When primed tubing is loaded into the pump hours before the start of infusion
- When tubing is left in the pump for hours after the end of infusion
- When utilizing Multi dose or Delay Option modes with significant delay periods

#### SUGGESTIONS FOR PREVENTION:

- Load tubing into the pump shortly before the start of infusion
- If the tubing has been closed in the pump for many hours it can be checked for possible occlusion prior to starting an infusion:
  - First, close the roller clamp
  - Open the pump's door
  - Remove and inspect the tubing, massaging it to open the lumen if necessary
  - Re-load the tubing into the pump and close the door
  - Open the roller clamp and begin the infusion

For further information contact:

Customer Advocacy (800) 854-7812 Ext. 7812 e-mail: customerfeedback@alarismed.com





# Recommended Priming Procedure Blood Sets for the Signature Edition® Infusion System



#### 1. PREPARE SET

- Close both roller clamps on the set.
- Slide the AccuSlide<sup>a</sup> Flow Regulator thumb clamp down until an audible "click" verifies it is in the fully closed position.
- Spike the priming solution container and hang.

#### 2. PRIME SET

- Open the roller clamp to the priming solution.
- Squeeze and release the blood filter chamber until it is filled to a level that completely covers the filter.
- Invert the AccuSlide Flow Regulator.
- Do not tap or flick the AccuSlide\* Flow Regulator during priming.
- Slowly prime the tubing. Priming slowly helps to minimize turbulence that can cause air bubbles to form.
- Close the AccuSlide\* Flow Regulator when priming is complete. Close the roller clamp to the priming solution.

NOTE: To remove air from injection ports, invert and tap while fluid is passing. To remove minute air bubbles from the SmartSite\* Needle-Free Valve ports, attach a luer lock syringe and aspirate the air. Always swab the valve septum with preferred antiseptic prior to accessing.

- Load the AccuSlide Flow Regulator into the Signature Edition Infusion
   System. Close latch fully to the left.
- Attach set to patient's vascular access device.
- Insert the second spike into the blood container and hang.
- Open the roller clamp to the blood container.

NOTE: The air contained within the leg of tubing to the blood spike can deplete the prime in the filter chamber. Back prime the leg of tubing to the blood spike with saline, or reestablish the prime in the filter chamber after the blood begins to infuse.

Program Rate and VTBI, then press RUN to begin infusion.

NOTE: Administration Set can also be used by gravity; adjust flow rate using the AccuSlide\* Flow Regulator.



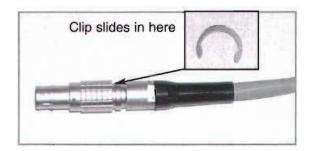






### **MedSystem III' Infusion Pump**

#### The AC adapter power cord



**Note:** A connector clip has been added to the AC adapter power cord.

(Shown with connector removed)



With the addition of the connector clip, the AC adapter *may no longer be removed* from the infusion pump, without first removing the connector clip.



To disconnect the power source, the infusion pump must now be unplugged from the outlet.

#### WARNING:

Trying to remove

the AC adapter

power cord from

the infusion

pump, without

first removing

the connector

clip, will cause

damage.

For more information, contact your Cardinal Health, Alatis' Products Sales Consultant at 1.800.482.4922, in Canada 1.800.387.8309, or visit our web site at www.cardinalhealth.com/alatis

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Printed on recycled paper with 10% post-consumer fiber.

Cardinal Health Alaris' Products 10:221 Wateridge Circle San Diego, California 92121

www.cardinalhealth.com/alaris



# **Immediate Impact on Preventing Harm**

IV medication safety systems focus on the most critical and costly errors — IV medication — and provide the greatest opportunity for continuous quality improvement (CQI) with actionable data.

#### WHY DO SOMETHING DIFFERENT?

#### Medication Errors Occur.

Medication errors account for at least 7,000 deaths in the United States every year, costing the health-care system \$2 billion through longer and costlier hospital stays." In a typical hospital, medication errors occur in nearly 1 of every 5 doses given to patients."

#### The Most Serious Potential for Harm Occurs with Intravenous (IV) Administration Errors.

Of the most serious and life-threatening potential advetse drug events (ADEs) 61% are IV drug-related. The IV route of administration for medications often results in the most serious medication error outcomes. Most high-risk drugs can be delivered via IV. IV administration errors account for 38% of errors—only 2% are intercepted. The errors made during administration often result in an ADE, while errors made earlier in the medication use process are less likely to reach the patient undetected. Recent data revealed rhat at an average 350-bed hospital a potential life-threatening IV error occurs every 2.6 days.

#### WHY DO SOMETHING NOW?

IV medication safety systems provide immediate results.

"Errors that cause great harm are in the IV area—they are really dramatic, and there is a great return on investment in reducing them. The speed to impact is better with IV medication safety systems than with anything we have seen."

-Charles R. Denham, MD, CEO, Health Care Concepts, Inc.

Compared with other approaches to medication safety, IV medication safety systems are much less complicated and take much less time to implement.

The ALARIS® Smart Infusion technology is among the few technologies that can have an immediate and dramatic impact on patient and caregiver safery hospital-wide. This safety solution can be built and expanded on from your existing platform and can be up and running in an average of 67 days with no additional FTE's. \*\*

#### Your hospital can't afford these types of errors.

The costs associated with medication errors are increasing. Studies have shown that the length of stay for a patient with an adverse drug event can increase by as much as 15 days."

Correspondingly, the cost of the average patient stay can rise by between \$16,000 and \$24,000.<sup>300</sup> Even more potentially severe are the expenses for medical liability and increasing insurance premiums. Recent research has shown that the average cost of defending a lawsuit from a preventable medication error is \$376,000.<sup>300</sup> Average jury awards in cases involving medication errors are \$636,844, and estimated pretrial settlements average \$318,400.<sup>300</sup> Even excluding litigation and patient injuty costs, potential adverse drug events can cost as much as \$2.8 million (1993 dollars) each year per hospital (depending on size of the hospital).<sup>300</sup>

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STEET BUS	Prescribing	Transcribing	Disper and Dist			istering nitoring
Technology Solutions	CPOE	P.I.S	Cabinets	Robots	Bar Code System	"Smart" Medley" System
Cost of Acquisition*	\$7.9M	\$0.5-1M	\$0.5-3M	\$1-3M	\$0.5-2M	\$1.2-1.5M
Time to Implement	18-36 Months	6-12 Months	4-6 Months	6-12 Months	6+ Months	90 Days

\*Estimated price based on a 350 bed hospital\*\*\*



In 1997, The Nebraska Medical Center was selected by ALARIS Medical Systems as one of two medical centers to help in the development of a new "smart" infusion safety lech-

Anecdotal reports and survey results indicate a high level of user satisfaction associated with the Medley™ Medication Safety System with the Guardrails Safety Software. These results suggest that the extensive staff input and human fac-

engineering that occurred during development of all components resulted in a system that is easy to use and well accepted by clinicians.

"Our nurses strongly
prefer using the Medley™
System over our previous IV
pumps. More
importantly, our data show
that use of the Guardrails\*
Software has prevented
several

potentially fatal medication errors. We feel that this technology is something nurses must have to protect both the patients and themselves against critical errors at the point of care."

— Al Gould, RN, MSN, CCRN, Clinical Nurse Specialist, The Nebraska Medical



EXHIBIT



#### SPECIAL ADVERTISING SECTION

There is also another chilling effect on your market that is difficult to recover from —negative PR. Imagine the cost implications which accompany a high-profile event.

# WHY THE ALARIS® MEDLEY™ MEDICATION SAFETY SYSTEM?

In 2002, the Institute for Safe Medication Practices (ISMP) Newsletter, Medication Safety Alert, was the first industry-wide report recognizing that new standards for "Smart Pumps" were yielding benefits that significantly help improve IV medication safety.<sup>34</sup> Since then ECRI has established criteria for these dose error reduction systems.

# ECRI has established Dose Error Reduction System criteria including:\*\*\*

- · Minimum of 8 profiles or "areas of use"
- · Comprehensive and hospital-configurable drug library
- Continuous display of drug name/dose on infusion pump
- Continuous indicator of doses infused outside of the limit ("Soft" override)
- Comprehensive log to record programming alerts, subsequent actions

Many of our customers' decisions to purchase ALARIS® smart technology (the Medley™ Medication System with the Guardrails® Safety Software) have been influenced by the ECRI report.

With increasing patient acuity in today's hospitals, new technologies, new drugs and more complex therapies have been introduced at an unprecedented pace. The Guardrails® Software offers clinicians a "safety net" so they do not have to rely on memory alone to determine correct dosing, or on the accuracy of a keystroke to ensure correct programming. IV medication safety systems accomplish this by checking that programming is within pre-established institutional limits before an infusion can begin. The Advisory Board has proven that pharmacist participation in hospital rounds reduces drug errors. Having IV medication safery systems at the bedside is like having a pharmacist in every room, at all hours of the day and night.

37,000 Medley™ Systems are in use in over 100 hospitals with over 240 million hours of run rime.

More than 20,000 nurses are protected by the Guardrails® Safety Software today. Currently, only 10-20% of events are captured by voluntary reporting systems.\*\* The Guardrails Safety Software ensures that every alert (near-miss) is reported and that each patient has dose error protection.

In addition, the Guardrails® Software offers the greatest degree of flexibility in designing different drug profiles. This includes determining the drugs, standard concentrations and dosing parameters required for each care area within a hospital, so you can continue to manage the unique needs of specific patients.

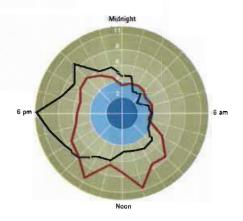
Presently, the ALARIS® Medley™ Medication Safety System with the Guardrails® Safety Software is the only IV medication safety system technology that enables hospitals to identify, track and most importantly, help prevent IV medication errors.

#### Best Practices in Your Hospital - Acting on the CQI Data.

When potentially harmful errors are averted, hospitals can turn their attention to an analysis of possible root causes. Finding the answers to questions such as this can help hospitals prevent future occurrences of errors.

In this representation of actual Guardrails® CQI data, a chronogram shows average Guardrails® Alerts over a 24-hour period sampling. The red line represents cumulative data from nine hospitals. The black line depicts data from a tenth hospital. Notice how few alerts occurred late at night and early in the morning. This probably reflects the fact that few dose changes or initiations of new medications take place during these hours. When physicians begin making morning rounds and the overall activity level picks up, more changes in drug therapy are ordered.

At the tenth facility—a children's hospital—



Graphic representation of actual CQI data.

Red line represents cumulative data from nine hospitals.

Black line represents data from a tenth hospital-a Children's Hospital.

#### SAFETY YOU CAN MEASURE"

The ALARIS® Medley™ System with the Guardrails\* Software helps your hospital to measure, sample and prevent harm over time across multiple devices, care units, or the entire hospital -making it possible to manage divisions and set policies hospitalwide, or departmentby-department based upon your hospital's care needs-giving you an easy way to track and report prevented errors to JCAHO and other regulatory institutions.

This software provides you a window to the bedside with builtin trigger tools and data collection that will help you with Continuous Quality Improvement (CQI) performance. If a dosage mistake has been made, it alerts the attending nurse immediately to the problem so that it can be corrected-- helping prevent potential harm to patients. It records the mistake, the time, the medication and how it was corrected. This electronic record enables your staff to immediately see where the medication errors are occurring and how often, so that they can begin to look for a pattern - a quantifiable record of past performance as well as a clear direction for future performance.

#### SPECIAL ADVERTISING SECTION

the data showed a significant spike at 6 p.m. This underscores the need to interpret data in a local context, since admissions at this hospital typically increase in the hours after school lets out.

Further analysis of CQl data revealed other contributing factors as well. For example, many of the alerts were associated with changes to hyperalimentation solutions, because new orders are written at this hospital between the hours of 4 and 6 p.m.

# Best practice changes hospitals have implemented based on CQI data include:

- Correlating medication delivery based upon the shift, time of day and day of the week.
- Standardizing rule sets and the variability of concentrations, complying with new JCAHO recommendations and mandates. This prepares hospitals for improved JCAHO-audit outcomes by complying with JCAHO best practices.
- Establishing more appropriate dosing limits for patients of different profiles.
- Setting parameters for overriding the soft limits of the programming of IV drugs based upon measurable utilization within the hospital.
- Reducing needle-sticks by switching to systems that do not accept needles makes the workplace for nurses and healthcare professionals safer and complies with JCAHO mandates and standards.
- Creating new educational and safety campaigns focused on the dangers of doses outside the hospital's best practice guidelines.

#### A Safety Platform You Can Build On™

From the beginning, we designed the Medley™ System with the Guardrails® Software as a platform you can build on. Our latest advancement is the ALARIS® Network and the ALARIS® Systems Manager, which allow hospitals to collect, interpret, and respond to CQI data more quickly and easily. The ALARIS® Network includes a central server and operating system kernel, plus standard wireless networking cards that are inserted directly into each Medley™ System. The ALARIS® Systems Manager, a server-based application running on the ALARIS® Network, eliminates the need



The Medley™ System

to manually transfer information to and from individual Medley™ System devices. The ALARIS® Systems Manager application allows for quick, simple uploads of data sets that have been revised based on actual clinical experience, or to incorporate new IV drugs. It also makes it possible to automatically download CQI data. This feature can be a tremendous help in meeting new Joint Commission regulations, which require hospitals to conduct proactive risk assessments of their medication use processes. Server-based applications can also support connectivity to other hospital IT systems.

#### **ROI for Your Hospital**

All of this means an increase in teturn on investment (ROI) for your hospital. The ALARIS® Medley™ System with the Guardrails® Software will help you save your hospital money, time and unnecessary patient risk by reducing the number of patients who experience an IV medication error.

#### Call Today

For more information call 800-609-6553 x6020 today or visit our website at: www.alarismed.com/mh11

where you will find case studies and more information about the ALARIS® Mediey™ Medication Safety System.

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ALARIS\*
MEDICAL SYSTEMS

Medication Safety

at the Point of Carew

ALARIS Medical Systems, Inc. Worldwide Headquarters, 10221 Wateridge Circle, San Diego, California 92121-2772 Fax: 1-858-458-7760 Customer Service: 1-800-482-4822 Website: www.alarismed.com



# Immediate Impact on Medication Safety

Celebrating 200 years of care



"With the nursing shortage, we can't afford to lose nurses to medication errors. Nurses deserve to have technology at the bedside, so they are not put in that situation."

Judy Peterman, MSN, RN



"It was apparent that the ALARIS" Medley " System was the first choice because of its immediate influence on patient safety... truly, speed to impact." Marianne Fields, MSN, RN, CNA

#### Call Today

For more information, call 800-609-6553 x6020 today or visit our website at www.alarismed.com/icaho8

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II Bates et al. The costs of adverse drug events in hospitalized patients. JAMA 1997; 277:307-11 IV medication safety systems focus on measurable results to help improve medication safety and best practices with actionable continuous quality improvement (CQI) data

#### SITUATION:

In 2001, a multi-disciplinary team of nurses, pharmacists, respiratory therapists, risk managers, physicians and others at St. Joseph's/Candler completed an ISMP Medication Self-Assessment. The team concluded that it needed to improve medication safety to better safeguard patients and nurses against intravenous (IV) medication errors. The team wanted a system that provided CQI data to help it redefine new IV medication safety best practices hospitalwide.

#### **KEY DECIDING FACTORS:**

#### Safety

The Medley™ Medication Safety System with the Guardrails® Safety Software is the only smart IV system that enables St. Joseph's/Candler to identify, track and most importantly, help prevent IV medication errors. It helps ensure that every alert is reported and that each patient is protected.

- · Patient Safety
- · Nurse Retention and Recruitment
- · Opportunity to Improve Standardization of Equipment and Treatment
- National data showing that 38% of medication errors occurred at the bedside, with the greatest risk for harm associated with IV infusion programming errors'

#### Financial Impact and ROI:

No hospital can afford to have IV medication errors. The costs associated with medication errors are increasing. Preventable adverse drug events can cost as much as \$2.8 million (1993 dollars) each year per hospital (depending on size of the hospital)."

#### SPEED TO IMPACT:

- Data set customization, staff training and product set-up were completed in approximately 65 days
- Implementation of the new infusion system on all inpatient areas (645 systems) was completed in less than 4 hours
- No additional FTEs were required for implementation.
- · Ability to have greater impact in shorter time at least cost

#### RESULTS

The Medley System with the Guardrails Software helped St. Joseph's/Candler quickly implement: Patient and Clinician Safety and Satisfaction Improvements:

- · Improve Patient Safety -- helping avoid potentially life-threatening and costly medication errors
- Initial CQI data gathered estimated that 406 infusion errors were probably prevented in 6 months
- Results from a Failure Mode Effects Analysis (FMEA) showed that implementation of IV medication safety systems reduced the risk priority score to 56 from a pre-implementation score of 210
- Clinician acceptance well received by the clinical staff with spot checks showing 98–100% compliance using the Guardrails\* Software
- With customizable patient profiles such as pediatrics, the two hospitals feel confident that all their children have protection no matter where they are within the health care system
- In keeping with the JCAHO "Speak Up" program nurses have improved communication with patients
  due to safety features that point out extra safety protection
- Improve nursing satisfaction and save nurses time- creating a better working environment with greater retention

#### A Positive ROI for St. Joseph's/Candler

- · Significant cost-savings were achieved by reducing infusion errors
- · Standardization of infusion devices and disposables
- . Numerous positive PR opportunities that have given the hospital a definite advantage in marketing

#### **ADVERTISEMENT**

# Immediate Impact on Preventing Harm

"Smart Pump" Technology focuses on the most critical and costly errors- IV medication- and the greatest opportunity for continuous quality improvement with actionable data

#### WHY DO SOMETHING DIFFERENT?

Medication Errors Occur. In 2002, more than 7,000 patient deaths resulted from medication errors, costing the health-care system \$2 Billion through longer and costlier hospital stays. Medication errors occur in nearly 1 of every 5 doses given to patients in the typical hospital.

The Most Serious Potential for Harm Occurs with Intravenous (IV) Administration Errors.

Almost all high-risk drugs are delivered via IV. Of the most serious and life-threatening potential adverse drug events (ADEs) 61% are IV drug -related." The IV route of administration for medications often results in the most serious medication error outcomes. Most high-risk drugs can be delivered via IV. IV administration errors account for 38% of errors-only 2% are intercepted. The errors made during administration often result in an ADE, while errors made earlier in the medication use process are less likely to reach the patient undetected. Recent data revealed that at the average 350-bed hospital a potential life-threatening IV error occurs every 2.6 days."

#### WHY DO SOMETHING NOW?

Smart Pumps provide immediate results. "Errors that cause great harm are in the IV area- they are really dramatic, and there is a great return on investment in reducing them. The speed to impact is better with smart pumps than with anything we have seen," said Charles R. Denham, MD, CEO of Health Care Concepts, Inc. Compared with other approaches to medication safety, smart pumps are much less complicated and take much less time to implement. This safety solution can be built and expanded on from your existing platform and can be up and running within 90 days with no additional FTE's.™ Your hospital can't afford these types of errors. The costs associated with medication errors are increasing. Studies have shown that the length of stay for a patient with an adverse drug event can increase by as much as 15 days. Correspondingly, the cost of the average patient stay can rise by between \$16,000 and \$24,000.x Even more potentially severe are the expenses for medical liability and increasing insurance premiums. Recent research has shown that the average cost of defending a lawsuit from a preventable medication error is \$376,000. Average jury awards in cases involving medication errors are \$636,844, and estimated pretrial settlements average \$318,400. This means that excluding litigation and patient injury costs, potential adverse drug events can cost as much as \$2.8 million each year per hospital (depending on size of the hospital).1

There is also another chilling effect on your market that is difficult to recover from --negative PR. Imagine the cost implications which accompany a high-profile event.

#### WHY ALARIS® SMART PUMP SYSTEMS?

Safety You Can Measure™ 25,000 Medley™ Medication Safety Systems in use in over 60 hospitals with 83 million hours of run time. This means that more than 18,000 nurses are protected by the Guardrails® Safety Software today. The ALARIS® Medley™ Medication Safety System with the Guardrails® Safety Software enables hospitals to identify, track and most importantly, help prevent IV medication errors over time across multiple devices, care units, or the entire hospital —giving you an easy way to track and report prevented errors to JCAHO, ECRI and other regulatory institutions.

Best Practices in Your Hospital- Acting on the Data The Medley<sup>M</sup> Smart Pumps incorporate continuous quality improvement (CQI) data to log all alerts, which allows a hospital to track programming errors, or "near misses," that have been averted and could have resulted in patient harm. CQI data provide a new source of information to assist you in identifying opportunities for new hospital best practices, such as establishing more appropriate dosing limits, correlating medication delivery based upon the shift, time of day and day of the week and standardizing rule sets. Because of this, smart pump technology is rapidly becoming the "gold standard" in IV medication safety.

A Safety Platform You Can Build On \*\* The ALARIS\*
Network and server-based applications can support infusion information management and provide a connectivity gateway to other hospital IT systems, making it possible to upload guidelines and download knowledge from actual clinical experience.

ROI for Your Hospital All of this means an increase in ROI (Return on Investment) for your hospital within 24 months. The ALARIS® Medley™ System with the Guardrails® Software will help you increase hospital profits, while saving your hospital money, time and unnecessary patient risk.

#### CALL TODAY

For more information, call 800-609-6553 x7529 today or visit our website at: www.alarismed.com/mh2, where you'll find case studies and more information about ALARIS® Smart Technology.

Spartanburg Regional Healthcare System, one of the top 100 most wired hospitals in the United States, discovered that using the ALARIS® Smart Pumps helped avert potentially significant medication errors. This system not only helped them achieve significant improvement in medication safety, it also helped them improve nursing satisfaction.

"With the resulting error prevention data, we can easily demonstrate to the community our improvements in, and commitment to, quality patience care" Raymond A. Shingler, Sr. Vice President/Chief Information officer for Spartenburg RHS.

"Note: This product has not yet been released for commercial sale. ALARIS Medica: Systems may not make this product available for commercial sale.

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ALARIS | Medication Safety
MEDICAL SYSTEMS | at the Point of Care
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2004 Media Plan

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